

What is claimed is:

1. A pharmaceutical formulation for pulmonary drug administration, comprising:  
a therapeutically effective amount of a bronchodilator;  
a therapeutically effective amount of a corticosteroid selected from the group  
5 consisting of mometasone and pharmacologically acceptable salts, esters and derivatives  
thereof; and  
optionally, a pharmaceutically acceptable carrier suitable for pulmonary drug  
administration.

10 2. The formulation of claim 1, wherein the bronchodilator has agonist activity for  
 $\beta_2$  adrenergic receptors.

15 3. The formulation of claim 2, wherein the bronchodilator is selected from the group  
consisting of albuterol, bitolterol, clenbuterol, fenoterol, formoterol, levalbuterol,  
metaproterenol, pirbuterol, procaterol, reproterol, rimiterol, salmeterol, terbutaline,  
derivatives thereof, pharmacologically acceptable salts and esters thereof, and combinations  
of any of the foregoing.

20 4. The formulation of claim 3, wherein the bronchodilator is selected from the group  
consisting of pirbuterol, levalbuterol, metaproterenol, derivatives thereof, pharmacologically  
acceptable salts and esters thereof, and combinations of any of the foregoing.

5. The formulation of claim 4, wherein the bronchodilator is pirbuterol acetate.

25 6. The formulation of claim 4, wherein the bronchodilator is pirbuterol  
dihydrochloride.

7. The formulation of claim 4, wherein the bronchodilator is levalbuterol sulfate.

8. The formulation of claim 4, wherein the bronchodilator is levalbuterol hydrochloride.

9. The formulation of claim 1, in the form of a dry powder.

10. The formulation of claim 9, wherein the bronchodilator is pirbuterol or a pharmacologically acceptable salt thereof.

11. The formulation of claim 10, wherein the bronchodilator is pirbuterol dihydrochloride or pirbuterol acetate.

12. The formulation of claim 9, wherein the bronchodilator is levalbuterol or a pharmacologically acceptable salt thereof.

13. The formulation of claim 12, wherein the bronchodilator is levalbuterol sulfate.

14. The formulation of claim 9, wherein the corticosteroid is anhydrous mometasone furoate.

15. The formulation of claim 9, wherein the carrier is present.

16. The formulation of claim 15, wherein the carrier is selected from the group consisting of fructose, galactose, glucose, lactitol, lactose, maltitol, maltose, mannitol, melezitose, myoinositol, palatinite, raffinose, stachyose, sucrose, trehalose, xylitol, hydrates thereof, and combinations of any of the foregoing.

17. The formulation of claim 16, wherein the carrier is lactose.

18. The formulation of claim 9, wherein the carrier is not present.

19. The formulation of claim 1, wherein the carrier is present.

20. The formulation of claim 19, in the form of an aerosol composition.

5           21. The formulation of claim 20, wherein the bronchodilator is pirbuterol or a pharmacologically acceptable salt thereof.

22. The formulation of claim 21, wherein the bronchodilator is pirbuterol dihydrochloride or pirbuterol acetate.

10           23. The formulation of claim 20, wherein the bronchodilator is levalbuterol or a pharmacologically acceptable salt thereof.

15           24. The formulation of claim 23, wherein the bronchodilator is levalbuterol hydrochloride.

25. The formulation of claim 20, wherein the corticosteroid is mometasone furoate monohydrate.

20           26. The formulation of claim 20, wherein the carrier is a propellant.

27. The formulation of claim 26, wherein the propellant is selected from the group consisting of a chlorofluorocarbon, a hydrochlorofluorocarbon, a hydrogen-containing fluorocarbon, a perfluorocarbon, a hydrocarbon, and mixtures thereof.

25           28. The formulation of claim 26, wherein the propellant is selected from the group consisting of dichlorotetrafluoroethane, trichloromonofluoromethane, dichlorodifluoromethane, chloropentafluoroethane, monochlorodifluoromethane, monochlorodifluoroethane, difluoroethane, CHF<sub>2</sub>CHF<sub>2</sub>, 1,1,1,2-tetrafluoroethane,

1,1,1,2,3,3,3-heptafluoropropane,  $\text{CF}_3\text{CF}_3$ ,  $\text{CF}_3\text{CF}_2\text{CF}_3$ , octafluorocyclobutane, propane, isobutane, *n*-butane, dimethyl ether, and mixtures thereof.

29. The formulation of claim 28, wherein the propellant is selected from the group consisting of difluoroethane,  $\text{CHF}_2\text{CHF}_2$ , 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane,  $\text{CF}_3\text{CF}_3$ ,  $\text{CF}_3\text{CF}_2\text{CF}_3$ , octafluorocyclobutane, and mixtures thereof.

30. The formulation of claim 19, in the form of a liquid.

31. The formulation of claim 30, wherein the liquid is an aqueous suspension.

32. The formulation of claim 30, wherein the bronchodilator is pirbuterol or a pharmacologically acceptable salt thereof.

33. The formulation of claim 32, wherein the bronchodilator is pirbuterol acetate or pirbuterol dihydrochloride.

34. The formulation of claim 30, wherein the bronchodilator is levalbuterol or a pharmacologically acceptable salt thereof.

35. The formulation of claim 34, wherein the bronchodilator is levalbuterol sulfate or levalbuterol hydrochloride.

36. The formulation of claim 30, wherein the corticosteroid is mometasone furoate monohydrate.

37. The formulation of claim 30, wherein the carrier is a sodium chloride solution.

38. The formulation of claim 1, in a unit dosage form.

5           39. The formulation of claim 38, wherein the unit dosage form is a hydroxypropyl methylcellulose capsule.

40. The formulation of claim 38, wherein the unit dosage form is a unit dose vial.

10           41. The formulation of claim 38, wherein the therapeutically effective amount of the bronchodilator is in the range of about 1  $\mu\text{g}$  to about 1500  $\mu\text{g}$ .

15           42. The formulation of claim 38, wherein the bronchodilator is pirbuterol acetate or pirbuterol dihydrochloride.

43. The formulation of claim 42, wherein the therapeutically effective amount of the bronchodilator is in the range of about 2.5  $\mu\text{g}$  to about 350  $\mu\text{g}$ .

20           44. The formulation of claim 38, wherein the bronchodilator is levalbuterol sulfate.

45. The formulation of claim 44, wherein the therapeutically effective amount of the bronchodilator is in the range of about 5.0  $\mu\text{g}$  to about 150  $\mu\text{g}$ .

25           46. The formulation of claim 38, wherein the bronchodilator is levalbuterol hydrochloride.

47. The formulation of claim 46, wherein the therapeutically effective amount of the bronchodilator is in the range of about 50  $\mu\text{g}$  to about 1300  $\mu\text{g}$ .

48. The formulation of claim 38, wherein the corticosteroid is anhydrous mometasone furoate or mometasone furoate monohydrate.

49. The formulation of claim 48, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1 µg to about 1500 µg.

50. A pharmaceutical formulation for pulmonary drug administration, comprising:  
a therapeutically effective amount of a bronchodilator selected from the group consisting of levalbuterol sulfate, pirbuterol acetate and pirbuterol dihydrochloride;  
a therapeutically effective amount of a corticosteroid selected from the group consisting of anhydrous mometasone furoate and mometasone furoate monohydrate; and  
lactose.

51. A method for treating a patient suffering from a condition, disease or disorder that is responsive to treatment with a bronchodilator/corticosteroid combination, comprising administering to the patient, via inhalation, a pharmaceutical formulation for pulmonary drug administration, wherein the formulation comprises:

a therapeutically effective amount of a bronchodilator;  
a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof; and  
optionally, a pharmaceutically acceptable carrier suitable for pulmonary drug administration.

52. The method of claim 51, via oral inhalation.

53. The method of claim 51, via nasal inhalation.

54. The method of claim 51, wherein the composition is administered only as needed to treat the patient suffering from the condition, disease or disorder.

55. The method of claim 51, wherein the condition, disease or disorder is selected from the group consisting of asthma, exercise-induced asthma, bronchitis, bronchospasm, rhinitis and emphysema.

56. A pulmonary drug delivery device, comprising: a pharmaceutical formulation comprised of a therapeutically effective amount of a bronchodilator, a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof, and an optional pharmaceutically acceptable carrier suitable for pulmonary drug administration; and a means for housing and dispensing unit dosages of the formulation.

57. The drug delivery device of claim 56, comprising a dry powder inhaler, metered-dose inhaler, nebulizer or pump spray bottle.

58. The drug delivery device of claim 56, in the form of a dry powder inhaler.

59. A dry powder inhaler for orienting and positioning a capsule containing a pharmaceutical formulation to be administered via inhalation, comprising:

a dispensing chamber containing a capsule of a dry powder pharmaceutical formulation comprised of a therapeutically effective amount of a bronchodilator, a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof, and a pharmaceutically acceptable carrier suitable for pulmonary drug administration;

a tube for receiving the capsule to be oriented and dispensed;

a ramp surface extending substantially across the tube from one wall to an opposite wall thereof; and

an elongate dispensing passage having a diameter less than that of the tube and sized to receive the capsule only when the elongate axis of the capsule is generally parallel to the axis of the passage, the passage extending from an inlet end formed by an aperture in the ramp's surface to a dispensing outlet, the passage being adjacent to one wall of the tube such that the axis of the passage is parallel to, but radially offset from, an axis of the tube,

whereby when the inhaler is positioned with the passage below the tube and the axis of the passage is substantially vertical, a capsule located in the tube is guided by the ramp surface towards the inlet end of the passage.

60. A dosage form containing a pharmaceutical composition for pulmonary drug administration, the pharmaceutical composition comprising:

a therapeutically effective amount of a bronchodilator;

a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof; and

optionally, a pharmaceutically acceptable carrier suitable for pulmonary drug administration.

61. The dosage form of claim 60, in the form of a capsule.

62. The dosage form of claim 61, wherein the capsule is a hydroxypropyl methylcellulose capsule.

63. The dosage form of claim 60, wherein the therapeutically effective amount of the bronchodilator is in the range of about 1  $\mu\text{g}$  to about 1500  $\mu\text{g}$ .

64. The dosage form of claim 60, wherein the bronchodilator is pirbuterol acetate or pirbuterol dihydrochloride.



65. The dosage form of claim 64, wherein the therapeutically effective amount of the bronchodilator is in the range of about 2.5  $\mu\text{g}$  to about 350  $\mu\text{g}$ .

66. The dosage form of claim 60, wherein the bronchodilator is levalbuterol sulfate.

67. The dosage form of claim 66, wherein the therapeutically effective amount of the bronchodilator is in the range of from about 5  $\mu\text{g}$  to about 150  $\mu\text{g}$ .

68. The dosage form of claim 60, wherein the bronchodilator is levalbuterol hydrochloride.

69. The dosage form of claim 68, wherein the therapeutically effective amount of the bronchodilator is in the range of about 50  $\mu\text{g}$  to about 1300  $\mu\text{g}$ .

70. The dosage form of claim 60, wherein the corticosteroid is anhydrous mometasone furoate or mometasone furoate monohydrate.

71. The dosage form of claim 70, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1  $\mu\text{g}$  to about 1500  $\mu\text{g}$ .

72. The dosage form of claim 60, wherein the carrier is present.

73. The dosage form of claim 72, wherein the carrier is selected from the group consisting of fructose, galactose, glucose, lactitol, lactose, maltitol, maltose, mannitol, melezitose, myoinositol, palatinite, raffinose, stachyose, sucrose, trehalose, xylitol, hydrates thereof, and combinations of any of the foregoing.

74. The dosage form of claim 60, wherein the carrier is not present.